MHRA Device Safety Information

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Handpieces used in the phacoemulsification technique of cataract removal: need for careful cleaning (DSI/2021/009)

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 24 Nov 2021. The original webpage can be accessed here. Scottish guidance has been referenced where appropriate.

Summary

Residue particles can end up in the patient's eye. For the attention of decontamination specialists, theatre practitioners and anyone involved with the cleaning and decontamination of medical devices.

Background

Cataract surgery is one of the highest volume types of planned surgery in the UK and the use of phacoemulsification is the method used in most cases. Hospital Episode Statistics (HES) data show that there were over 10,000 phacoemulsification extractions of lenses from 2017 to 2020.

The MHRA has ongoing concerns regarding particulates found in the eye during or following surgery, with the potential to lead to post-operative infection such as endophthalmitis or toxic anterior segment syndrome (TASS). Particles could be caused by several factors including cleaning and environmental issues, for example water quality and/or air filtration in theatre.

This guidance aims to minimise the risks associated with inadequate or improper cleaning and decontamination of phacoemulsification (phaco) handpieces.

In the period from 2017 to 2020 the MHRA received 38 reports of particles found in the eye either during or after surgery. Investigation found that these particles were of various substances such as organic matter, crystalline material, fibres, or pieces of plastic. In most cases it is difficult to determine the source of the particle. However, there is some evidence from manufacturer investigation and published literature to suggest that:

- particles can become trapped as residue in the handpiece throughout the cycle of clinical use and decontamination
- processes such as pre-cleaning flushing, and appropriate cleaning chemistries can reduce the risk of material becoming lodged within the handpiece
- extended time taken to process and transport the handpieces for in-depth cleaning may contribute to organic and crystal particles being trapped and then dislodged into the eye of a patient during subsequent use.

MHRA Action

During 2020 the MHRA worked with leading manufacturers of phacoemulsification handpieces to ensure that the cleaning and decontamination instructions supplied with the devices were amended and updated to meet the latest regulatory requirements for safety and performance for CE marked devices.

Actions

Procurement

- Review cleaning instructions before purchase. Ensure that the pre-purchase process involves commercial, clinical (operator and other theatre staff) and cleaning/decontamination experts as set out in SHTM 01-01 Decontamination of medical devices in a Central Decontamination Unit
- Ensure all consumables, including processing chemicals, are compatible with your phacoemulsification system.

Procedures and staff training

- Organisations should have standard operating procedures (SOPs) for reprocessing that include documented approval for products to be used and an escalation process.
- Ensure that staff responsible for pre-cleaning and decontamination and handling these devices have received appropriate training in accordance with the manufacturer's instructions through a local training plan. Keep an up-to-date log with initial and refresher training intervals.

After use

With close attention to the manufacturer's most up-to-date cleaning instructions:

- immediately flush phaco handpieces after the end of each use
- transfer them to the decontamination facilities as soon as practically possible
- position the handpiece within the washer and autoclave, using appropriate caskets as necessary
- ensure devices that require special cleaning are identified as such and cleaned appropriately.

Reporting Incidents

Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate (report here for Scotland)

References

Additional Guidance applicable in Scotland

- SHTN 00-04 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services
- SHTM 01-01 Decontamination of medical devices in a Central Decontamination Unit
- SHTM 04-01 Water safety for healthcare premises
- SHTM 03-01 Ventilation for healthcare premises

- GUID 5017 Decontamination of medical devices (surgical instruments) Guidance for service users - Supplement to SHTM 01- 01 Decontamination of medical devices in a Central Decontamination Unit
- GUID 5014 Decontamination – Requirements for compliant CDUs
- SHPN 13 Scottish Health Planning Note 13 Part 1 Decontamination Facilities: Central Decontamination Unit

Additional UK Guidance

- MHRA's Managing Medical Devices - see sections 3, 5, 6, 7 and 9.
- ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.

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